



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 241425

Product:	NYSTATIN
Lot:	241425
Expiry date:	30/06/2027
Reference:	Cumple PhEur11.5
Synonyms:	
Formule:	C47H75NO17
Poids moléculaire:	926,1 g/mol

Assay	Result	Specification	
Identification	Conform (B,E)		
Organoleptic properties	Conform		
Absorbance	0,85	$\geq 0,60$	
Composition (HPLC)	Conform		
Elemental impurities	Conform	Test PhEur	#
Loss on drying	3,3 %	$\leq 5,0 \%$	
Sulphated ashes	1,2 %	$\leq 3,5 \%$	
Antimicrobial power	6369 UI/mg s.p.s.	≥ 5000 UI/mg s.p.s.	
Nystatin A1	91,1 %	$\geq 85,0 \%$	
Any other compound	2,9 %	$\leq 4,0 \%$	
Residual solvent: Methanol	< 3000 ppm	≤ 3000 ppm	#
Residual solvent: acetone	< 5000 ppm	≤ 5000 ppm	#
Residual solvent: 1-Butanol	< 5000 ppm	≤ 5000 ppm	#
Nitrosamine impurities	Conform	Test PhEur	#

Organoleptic characteristics: Yellow or slightly brownish powder, hygroscopic. Practically insoluble in water, freely soluble in dimethylformamide and in dimethyl sulfoxide, slightly soluble in methanol, practically insoluble in alcohol.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 08/08/2024

Judgement:
APPROVED

Responsible: R. Masanas

Technical director: Montserrat Enrique

Manufacturer: F01035 VUAB PHARMA

Manufacturer batch: 19800624

Produit	Nom	Capacité	Lot
1162608	NISTATINA	10 g	241425-F-1
1162608	NISTATINA	10 g	241425-F-2

1162609	NISTATINA	25 g	241425-G-1
1162609	NISTATINA	25 g	241425-G-2
1162615	NISTATINA	1 kg	241425-P-1
1162615	NISTATINA	1 kg	241425-P-2
1200213	NISTATINA	100 g	241425-J-1
1200213	NISTATINA	100 g	241425-J-2

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

ACOFARMA DISTRIBUCIÓN, S.A.
C/ Llobregat, 20 - 08223 Terrassa (Barcelona)
Tel./ 93-736.00.88
www.acofarma.com

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